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Memorandum

Date: May 23, 2002

To: the Record

From: Dominic Mancini

cc. Clark Nardinelli, Richard Williams, Kenneth Falci

Subject: Technical Analysis Supplement for the Definition of the Term "Healthy".

1) Examples of the Sodium Content of Cheeses

FDA visited several Washington, DC, area grocery stores to search for "healthy" cheeses and to gather sodium content and serving size information for cheese types. We found no "healthy" cheeses, and confirmed with an informal telephone inquiry that the only producer of "healthy" cheese found in the 1999 market study no longer produces "healthy" cheese. Table 1 summarizes our findings. All Mozzarella cheeses that we sampled met the more-restrictive, second-tier sodium levels for individual foods of 360 mg of sodium per adjusted sample size, as reported in the last column of Table 1.

Table 1: Cheese Examples

Product Type	Sodium (mg)	Serving Size (g)	Adj Sodium per 50 g
Light Mozzarella Shredded	200	28	357
Cube Mozzarella	100	30	167
Cube Mozzarella	200	28	357
American Cheese Slice	320	21	761
Swiss Cheese Slice	290	21	690

2) Technical Cost Analysis for Meals/Main Dishes.

Note on the store-based and web-based samples. Either FDA or USDA may regulate frozen dinners and other meal and main dish products, based on the amount of traditional meat the products contain. This sample does contain products that are regulated by the USDA. If meat-based meals had systematically lower or higher sodium levels in the overall market (they do not in these samples), the results could be biased.

a) Sample 1 Analysis. FDA collected price, quantity, sodium content, market position, brand, and health claim information for all 106 goods in the first sample, and ran a series of simple ordinary least squares (OLS) regressions to measure the impact of different characteristics of the products and market on sodium content.

Table 2. Sodium Content Regression (R^2= 0.73)

Brand	Coefficient	(Standard Error)
Constant	593	(-27)
Healthy	-42	(-44)
Claims 2	129	(-52)
Claims 3	-28	(-54)
Claims 4	22	(-59)
Bargain 1	72	(-59)
Bargain 2	230	(-56)
Normal 1	878	(-85)
Normal 2	466	(-42)

Since market segment and health claim information operate at the brand level, we were unable to distinguish the impact of each brand from that of making a certain health claim or choosing a certain market position. Functionally, any dummy variables added to the model that described the market or a health claim were collinear with one or a combination of brand dummy variables, causing one or the other group to be dropped.

Since brand dummies are the only variables in this regression, the point coefficient estimate for each of the brand dummy variables is exactly equal to the average amount of sodium for that brand in a non-regression setting. For example, taking the mean for all products in the excluded category would yield 593 mg per meal, exactly the information gathered from the regression.

However, the regression yields additional useful information: the variation in sodium content unexplained by the brand name, and whether the difference in sodium content is statistically significant, although we argue below that this is a bit misleading for the sodium analysis. The brand dummy variables explain the variation in sodium remarkably well, with an unusually high R^2 (0.73) for this type of analysis. This is evidence that brand, including a "healthy" brand, is a strong signal of sodium content.

Relative to the excluded category, which is a major producer of "claims" segment products not using the specific "healthy" claim, the point estimate is -42 mg, and this is also lower than every other dummy variable. This difference is not statistically significant at standard levels, but actually is still fairly strong evidence that the health claim producer has the lowest sodium products on the market. The three levels of sodium per meal for the major "claims" segment of the market are 593 mg for the excluded category, 722 mg for the non "healthy" claims competitor (593 + 129 mg dummy coefficient), and 551 mg (593 - 42 mg dummy coefficient) for the "healthy" brand.

Why is the evidence still strong with a statistically insignificant variable? This point is best explained by presenting the equation for the variance[1] (t statistic squared) of a coefficient estimate in OLS, under the assumption of 1 slope coefficient estimate b and residual ϵ:

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[1] Greene, W. 1993. *Econometric Analysis, 2nd Edition*. Macmillan Publishing Company.

(1) $Var(b) = \sum_{n=1}^{N} \epsilon_n / (N-2) \sum_{n=1}^{N} (x_i - \bar{x})^2$

Although a significant coefficient would be a strong indicator of true differences in this model, a standard hypothesis test based on the t-statistic tests the difference between the coefficient value and zero, so the implicit assumption is that the expected value of the coefficient is zero. For "healthy" brand products, which have a legal restriction on the amount of sodium they contain, this is not the case. An optimal test would be if the coefficient were equal to some theoretical negative value, and if it were truly close to that value the numerator that depends on the OLS residual would be smaller. Another way to think about this issue is that the denominator of the variance depends on the number of observations: as the number of observations in the sample increases, it is almost certain that additional healthy brand meals will have lower sodium, again since they are required to by the compliance period regulation. The variance is inversely related to the number of observations in the estimation, and OLS is unbiased regardless of distributional assumptions, so we can be fairly certain that the results would be stronger purely as a result of adding more products to the observational basket.

b) Market Share Percent Calculations. Table 2 presents the sales levels and calculations used to estimate market shares for the scenario analysis. Total sales in the frozen dinner market were approximately $5,300,000,000 in 1999.

Table 3. Market Share Calculations for Scenario Analysis

Product	(1) 1999 $ Sales	(2) Total Market Share (1) / 5.3 b	(3) Normalized Market Share. (2)/Σ(2)
Healthy Brand	480 million	9.1 %	44.9 %
Claim Brand 1	559 million	10.5 %	52.2 %

Claim Brand 2	31 million	.6 %	2.9 %

c) Sample 2 Analysis. The second sample is designed to verify the results of the first sample. Since both are quite small, they may be unrepresentative; however, the consistency of the results strengthens our conclusions. This sample is a selection of all 26 items featured on the August 2, 2000 web site[2] of the leading producer of "healthy" products affected by this rule, and a sample of 10 items of lower sodium alternatives of a non-healthy claim competitor also featured on their web site on August 2, 2000[3]. We designed the second set of products as the "best sodium alternative," since they are taken from the low sodium selections among the products with the lowest sodium besides the healthy brand in the first sample. Since this would be what is available to a person consciously selecting low sodium as the most important choice, this will overstate the cost of the amendment.

Once again, the 600 mg limit for "healthy" does not reflect the actual average number of mg sodium in meal products for these two producers. Table 3 presents descriptive statistics for the two brands.

Table 4. Sodium Intake Statistics for the Web-based Sample 2

	Healthy	Low Sodium Alt.
Average per brand	512 mg	527 mg
Percent of meals with 600 mg or over per brand	9.7 (all at 600 mg)	30.0
Percent of meals with 480 mg or over per brand	51.6	70.0

These levels are substantially lower than the grocery sample above. This is because we

[2] http://www.healthychoice.com/kitchen/html/kitchen.cfx

[3] http://www.leancuisine.com/product_info.cfm

deliberately chose a low sodium second column. This sample is a stress test of the first sample and conclusions, so the assumptions must be favorable to the current rule. Also, web sites are advertisement tools, so some selection towards lower sodium featured products may be at work. The "healthy" product is again the lower sodium alternative. Under perfect reformulation, comparable to scenario 2, the average amount of sodium among the "healthy" brand product line would drop to 461 mg per meal, and using the same market share in the scenarios for sample 1 (again normalized to 1), the average meal consumed in the claims segment of the market would drop from 520 mg (512*.46 + 527*.54), to 496 mg (461*.46 + 527*.54), a 24 mg drop that is somewhat lower than the first sample result. If the healthy producer lost 25% of its market share, comparable to scenario 6, the overall increase would be 17 mg per meal under the amendment, which is close to the 22 mg difference in the first sample results.

d) Health Effects of 22 mg sodium. This is the calculation behind the lives saved statement in the main analysis.

(1) Total $ sales of health placed dinners in 1999 [sum of table2, column 1 above]:	1.1 b
(2) Total units sold of health placed dinners in 1999 [(1)/$2.92 per meal]:	366 m
(3) Sodium increase in US due to amendment [22 mg * (2)]:	8.1 b mg
(4) Sodium change per person per day [(3)/275m/365 days] :	.008 mg
(5) Percent of INTERSALT[4] risk level [(4)/2300mg]:	3.5 E-05
(6) Lives lost due to amendment [(5)*12000]:	0.42

[4] INTERSALT is the major international study linking sodium with hypertension and the resultant coronary heart disease and stroke. The impact on blood pressure and disease identified in this study was based on a 2300 mg change in sodium intake per day. The proposed rule's sodium increase is expressed as a percent of this 2300 mg, and we assumed that the health impact was also a linear function of the 2300 mg impact identified of 12000 lives per year in the US.

3) Technical Benefit Analysis for Meals and Main Dishes

a) Re-branding Costs Avoided. FDA used the Washington DC based sample of 106 meals and main dishes explained above to re-estimate the healthy brand price premium for 2000 in the Table 4 regressions. Also, since we have no reason outside of the model itself to expect a difference in price within the same market niche, i.e. the price is completely determined by the market whereas current regulations restrict sodium content, a null hypothesis of zero difference in price is a much more reasonable assumption to make than in the sodium analysis above, and the t-statistics and standard significance levels will be more useful.

Table 5. Price Regression (R^2=0.63)

Brand	Coefficient	Standard Error
Constant	2.84	(0.08)
Healthy	0.32	(0.14)
Claims 2	-0.10	(0.16)
Claims 3	0.61	(0.17)
Claims 4	0.48	(0.19)
Bargain 1	-1.09	(0.19)
Bargain 2	-1.44	(0.18)
Normal 1	0.31	(0.27)
Normal 2	0.05	(0.13)

As in the sodium regressions, brand explains price differences very well. According to table 4, the "healthy" branded competitor has a significant $0.32 premium over the excluded dummy category. At average serving sizes of 10 oz., this translates into a $0.51 premium per 16 oz, which is very close to the $0.57 premium estimated in 1994.